REMARKS

The Office action of July 24, 2008 has been carefully reviewed. Applicant hereby respectfully requests that the finality of the office action be withdrawn as it is clearly premature. By the present amendment, Applicant amended claims 87-91 and 94-96. Finally, Applicant disagrees with the rejection of claims 72-77 and 80-82 under 35 U.S.C. section 102 for the reasons discussed in the following.

Final Rejection Premature

The section 102 rejection based on prior art reference Iketani et al. is presented to Applicant for the first time and yet it has been made final without affording Applicant any opportunity to response. It is therefore premature.

The Examiner asserted that the above new rejection was "necessitated by the Applicant's amendments filed on 6/20/08." This boilerplate assertion contradicts the facts of this case. The only change to the claims made by Applicant's 6/20/08 amendment is the deletion of one of the three *Trichosanthes* species from the claims as shown below:

72. (Currently Amended) A pharmaceutical composition comprising an extract from ~~*Trichosanthes kirilowii Maxim,*~~ *Trichosanthes rosthornii Harms* or *Trichosanthes japonica Regal*, wherein said extract induces hemoglobin synthesis in human K562 cells and said extract is prepared by a method comprising the steps of:

(a) contacting ~~*Trichosanthes kirilowii Maxim,*~~ *Trichosanthes rosthornii Harms* or *Trichosanthes japonica Regal* with a first solvent consisting of an aqueous solution of from 50% to 70% ethanol to form a mixture;

(b) heating the mixture to form a liquor; and

(c) concentrating the liquor to form a first syrup.

Clearly this deletion has nothing do with Examiner's new rejection based on Iketani et al. Furthermore, the Iketani reference, on which the new rejection is based, is not new to the Examiner but had already been cited by the Examiner for a previous rejection (06/25/2007), which was later withdrawn by the Examiner. Therefore, this is not a situation where the new rejection is based on a newly submitted IDS.

Applicant respectfully submits that it is premature to make this office action final and the finality thereof should be withdrawn. If insisting on its finality, the Examiner is requested to make the determination on finality final to afford Applicant an opportunity to file a petition. If finality of the last Office action is withdrawn, the concurrently submitted Notice of Appeal should be deemed as not being filed and the fee paid for filing Notice of Appeal should be refunded to Applicant.

Amendment to Claims 87-91 and 94-96

The claims 87-91 and 94-96 have being amended to take the form of method claims as the Examiner gives no patentable weight to the steps of the process recited in the product-by-process claims. As the amendment relating only to the form of the claims, no new matter is introduced. In addition, as the Examiner gives no patentable weight to the recitation "wherein said extract induces hemoglobin synthesis in human K562 cells," it is removed from the preamble of the claims 72 and 87.

It is respectfully submitted that by taking into consideration the process steps recited in the claims, the Iketani reference and all other references of the record do not, alone or in combination, anticipate or suggest the subject matter of the present invention as claimed in claims 87-91 and 94-96.

Section 102 Rejection Erroneous

Claims 72-77 and 80-82 are rejection as being anticipated by the Iketani et al. reference. The Examiner's *prima facie* case of anticipation is largely presented by the following few conclusive statements.

> Iketani et al teach that dried seed of *Trichosanthes japonica. Trichosanthes bracteata*, etc. (a plant of Cucurbitaceae family) is extracted with a solvent such as water, methanol, ether, benzene, etc., and subjected to column chromatography. The obtained crude fraction is purified by chromatography to obtain the objective compound (see Abstract, the rejection is based on the Abstract, full translation has been ordered).
>
> These are product-by-process claims. The water, methanol extract of *Trichosanthes japonica* inherently contains the pharmaceutical composition that is being currently claimed, and the composition is deemed to have the physical properties such as retention time on high performance liquid chromatography.

Clearly, not only the above conclusive statements are legally insufficient to make a *prima facie* case of anticipation, which requires the anticipation analysis be "conducted on a limitation by limitation basis, with specific fact findings for each contested limitation and satisfactory explanations for such findings" (*Gechter* v. *Davidson*, 43 USPQ 2d, 1030, 1035 (Fed. Cir. 1997)), but also the statements are factually erroneous.

Iketani teaches a process of isolating a "novel glycerol derivate" from plant species (1) *Trichosanthes kirillowii Maximowicz* var. *japonicum Kitamura*, (2) *Trichosanthes bracterata Voigt*, or (3) *Trichosanthes kirillowii Maximowicz* (last paragraph, page 3, English translation of the Iketani reference), while claims 72-77 and 80-82 of the present application all relate to a pharmaceutical composition having an extract from plant species *Trichosanthes rosthornii Harms* or *Trichosanthes japonica Regal.* First of all, the two sets of plant species are clearly different. How can the disclosure of Iketani anticipates the above claims when different plant species are involved?

Secondly, what is the factual basis to state that the transient water or methanol extract which occurs in the process of isolating a glycerol derivate taught by Iketani "inherently contains the pharmaceutical composition that is being currently claimed,"

particularly when, as it is the case with claim 77, the pharmaceutical composition claimed contains a pharmaceutically acceptable carrier or adjuvant? Applicant believes that Iketani does not even mention a pharmaceutically acceptable carrier or adjuvant. For any one of the above cited wrong facts, the section102 rejection based thereon cannot stand.

Applicant respectfully submits that the section 102 rejection made in this case based on the Iketani reference is legally insufficient and factually erroneous. Reconsideration and reversal of the rejection is earnestly solicited

Respectfully submitted,

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George G. Wang, Ph.D., Reg. No.: 41,419
Attorney for Applicant

WILKINSON & GRIST
6th Floor, Prince's Building
Charter Road, Hong Kong

Telephone (852) 2905-4786
Telefax (852) 2520-2090